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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,182

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Marcia L. Kalish

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EXAMINER

PENG, BO

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/552,182

**Applicant(s)**

KALISH ET AL.

**Examiner**

BO PENG

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-29, 36 and 41-59 is/are pending in the application.
- 4a) Of the above claim(s) 47-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-29, 36, 41-46 and 55-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This Office Action is in response to the amendment filed January 13, 2009. Claims 26-29, 36 and 41-59 are pending. Claims 47-54 were previously withdrawn from consideration. Claims 26-29, 36, 41-46 and 55-59 are considered in this Office action. Applicant elected species of SEQ ID NOs: 1 and 14.

### ***Sequence Listing***

2. The sequence listing, submitted on January 13, 2009, has been accepted.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. **(Prior rejection-maintain)** The rejection of Claims 26-29, 36, 41-46 and 55-59 under 35

U.S.C. 103(a) as being unpatentable over Simon, *et al.* (AIDS Res. And Hum Retroviruses, 17(10):937-952, 2001); in view of Guertler (6,566,513), Tam (PANS, 1988) and Kim (2001), is **maintained** for the reason of record and the reasons set forth below.

In response to Applicant's argument:

5. Applicant argues (1) that Simon *et al.* combined with the secondary references do not teach or suggest all claim limitations by pointing out deficiencies in each of the cited references individually. Applicant argues (2) that there was no motivation to combine the references, and combining the cited references does not result in the present invention of multiple antigenic peptides (MAP) format and peptide sequences of less than 16 amino acid residues. Applicant asserts that there is nothing in any of the cited references which might suggest that smaller peptides could effectively detect and differentiate isolates from different primate immunodeficiency virus lineages.
6. Applicant's arguments have been fully considered but they are not persuasive. In response to Applicant's argument (1), this is an obviousness rejection under 35 U.S.C. 103, not an anticipation rejection. As such, it is agreed that none of the cited references disclose each limitation of the claimed features. The rejection is made instead on the basis that the cumulative teachings of the references renders the claimed features obvious to those of ordinary skill in the art. The Applicant's pointing out deficiencies in each of the references individually is therefore not persuasive.
7. In response to Applicant's argument (2) that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some

teaching, suggestion, or motivation to do so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the present case, Tam teaches that the MAP system, which comprises multiple copies of peptides on a solid-phase peptide, has increased detection sensitivity in detecting antibodies, compared with the conventional approach using a monomeric epitope peptide, see e.g. Abstract. Tam also teaches that 12- to 17-mer peptide residues were found to have optimum binding to antibodies, see e.g. Abstract and Para 1, left col. p. 59, and Fig. 6.

8. Kim teaches a MAP format comprising “an immunodominant region of a transmembrane envelope protein of a primate immunodeficiency virus” (Claim 26) for detecting HIV-1, wherein the MAP comprising 13-mer peptides derived from the V3-loop of HIV gp120, see whole document, particularly Abstract. In a side-by-side comparison study, Kim shows that a MAP format immunological assay is more sensitive and efficient than an indirect enzyme immunoassay of a monomeric peptide.

9. Both Simon and Guertler teach the peptides derived from the cysteine loop region of gp41/gp36 of SIV, which is another art-recognized immunodominant region of HIV and SIV, are particularly important for diagnosis of different strains of HIV and SIV, see e. g. Guertler col. 4 and Table 1. Simon teaches use of such SIV peptides for detecting and differentiating amongst various SIV strains, wherein the peptides comprise antigenic sequences 100% identical to the instant detection peptide SEQ ID NO: 1, and the instant differentiation peptide SEQ ID NO: 14, respectively (The sequence alignment was provided in the previous Office action).

10. In view of the combined teaching of the cited references, one of ordinary skill in the art would be motivated to use a MAP format in an enzyme immunoassay for detecting different SIV strains in order to take advantage of the high sensitivity and efficiency of a MAP system. There would have been a reasonable expectation of success in making MAP constructs comprising antigenic SIV peptides shorter than a 16-mer, such as SEQ ID NO: 1 and 14, given the knowledge that 12- to 17-mer peptide residues are optimum binding to antibodies in MAP system, as taught by Tam, given the knowledge that MAP comprising 13-mer peptides derived from HIV gp120 V3 loop has been successfully used for detecting HIV, as taught by Kim, and also given the knowledge that the SIV peptides, which comprise the instant SEQ ID NO:1 and 14, have been used successfully for discrimination of SIV serogroups, as taught by Simon and Guertler. Since the structural features and properties of the claimed enzyme immunoassay construct have been taught and suggested by the cited references, it would be obvious to those of ordinary skill in the art to make the claimed MAP. Thus, Applicant's argument is not persuasive. The rejection is maintained.

***Remarks***

11. No claim is allowed. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/  
Examiner, Art Unit 1648